Carbosten with Promethazine® Syrup
(Carbocisteine and Promethazine Hydrochloride)

Composition
Each 5ml contains:
Carbocisteine 100mg
Promethazine Hydrochloride 2.5mg
Pharmacology
Carbocisteine is a mucolytic agent which decreases the viscosity of the mucus, fluidizes it and facilitates its evacuation, thus promoting recovery.
As a mucoregulatory agent, it helps regenerate the impaired bronchial mucosa. Promethazine, a phenothiazine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and some serotonin-antagonist properties. Promethazine hydrochloride is used for the symptomatic relief of allergic conditions including urticaria and angioedema, rhinitis and conjunctivitis, and in pruritic skin disorders.
Pharmacokinetics
Carbocisteine is rapidly and well absorbed from the gastrointestinal tract with peak plasma concentrations occurring 90 to 120 minutes after an oral dose. It appears to penetrate into lung tissue and respiratory mucus. Carbocisteine is excreted in the urine as unchanged drug and metabolites. Acetylation, decarboxylation, and sulfoxidation have been identified as the major metabolic pathways. Sulfoxidation may be governed by genetic polymorphism.
Promethazine is well absorbed after oral administration. Peak plasma concentrations have been observed 2 to 3 hours after administration by these routes, although there is low systemic bioavailability after oral administration, due to high first-pass metabolism in the liver. Promethazine crosses the blood-brain barrier and the placenta, and is distributed into breast milk. Values ranging from 76 to 93% have been reported for plasma-protein binding. Promethazine undergoes extensive metabolism, predominantly to Promethazine sulfoxide, and also to N-desmethylpromethazine. It is excreted slowly via the urine and bile, chiefly as metabolites. Elimination half-lives of 5 to 14 hours have been reported.
Indication
Carbosten with promethazine syrup is used in unproductive and irritating coughs particularly in nocturnal coughs.
Dosage
To be taken orally.
Adults: 3 to 4 spoons (15 ml to 20 ml) three times a day.
Children: 2-5 years of age ½ to 1 spoon (2.5 ml to 5 ml) four times a day. 6-12 years of age 1½ to 2½ spoons (7.5 ml to 12.5 ml) three times a day. 12 -15 years of age 2½ to 3 spoons (12.5 ml to 15 ml) three times a day.
Contraindications:
Known allergy to one of the ingredients of Carbosten with Promethazine and particularly to antihistamines or parabens; former or recent agranulocytosis; urination difficulties due to the prostate gland or another cause; certain forms of glaucoma. Children <2 years (due to the potential for fatal respiratory. depression).
Carbosten with Promethazine must generally not be used, unless otherwise indicated by the doctor, in combination with sultopride.
Special warnings and precautions for use:
In the event of long-standing disease of the liver or kidneys, consult the doctor for dosage adjustment.
Intake of Carbosten with Promethazine requires a medical opinion: In the event of ulcer of the s stomach or duodenum; serious heart disease; epilepsy; in children, in the event of asthma or gastroesophageal reflux; in the elderly, who are predisposed to constipation, dizziness or drowsiness presenting with prostatic disorders.
Inform the doctor before initiating treatment.
Refrain from alcoholic beverages or drugs containing alcohol throughout the duration of treatment.
Preferably avoid exposure to sunlight during the treatment.
In the event of diabetes mellitus or a low-sugar diet, take the sugar content of the syrup into account in the daily ration: 3 g of sugar/measuring spoon and 9 g of sugar/tablespoon.
If in doubt, do not hesitate to ask for the doctor's or pharmacist's advice.
When to Seek Medical Advice: Consult a doctor when: Experiencing long-standing disease of the liver or kidneys; experiencing one of the situations described previously; pregnant or breastfeeding; experiencing side effects of Carbosten with Promethazine (see Side Effects); have taken Carbosten with Promethazine for a few days in a row and the condition is not improving; if cough becomes productive or is accompanied by fever; have taken an overdose of Carbosten with Promethazine.
Interaction with other medicinal products and other forms of interaction:
In order to prevent possible interactions between several drugs and in particular, sultopride, systematically report any on-going treatment to the doctor or pharmacist. Carbosten with Promethazine contains promethazine (an antihistamine) and carbocisteine. Avoid other products containing these drugs so that the maximum recommended dose for each drug is not exceeded.
Pregnancy and lactation:
Pregnancy: *If* the patient becomes pregnant during treatment, consult the doctor. The doctor will decide whether it is necessary to maintain treatment through the pregnancy. Towards the end of pregnancy, misuse of Carbosten with Promethazine may have adverse effects on the newborn. In consequence, always ask the doctor's or pharmacist's advice before using this drug and never exceed the prescribed dose and treatment duration.
Lactation : Carbosten with Promethazine is excreted in breast milk. Do not take this drug if breastfeeding.
Use in children: Carbosten with Promethazine should be used with caution in children ≥2 years.
Effects on ability to drive and use machines:
Attention, particularly that of drivers and machine users, is drawn to the possibility of drowsiness associated with the use of Carbosten with Promethazine. This phenomenon is accentuated by consumption of alcoholic beverages**.**
Adverse reactions:
Like all active products, Carbosten with Promethazine may induce more or less unpleasant effects. Some of these effects require immediate discontinuation of treatment and consultation with a doctor. Allergic Reactions: Skin rash type (erythema, eczema, purpura, urticaria); asthma attacks; Quincke's edema; anaphylactic shock; phenomena of sensitization of the skin under the action of sunlight; marked reduction in the white blood cells which give rise to development or recurrence of fever whether or not accompanied by signs of infection; abnormal decrease in the platelets in the blood which may give rise to bleeding from the nose or gums. Other adverse effects are more frequent: Drowsiness, reduced alertness more marked at the start of treatment; memory or concentration disorders, dizziness (more frequent in elderly subjects): Motor incoordination, tremor; confusion, hallucinations, dry mouth, visual disorders, urinary retention, constipation, palpitations, fall in blood pressure. Possibility of gastrointestinal intolerance phenomena (stomach pains, nausea, diarrhea). If these occur, a reduction of dosage is recommended. More rarely, but particularly in infants, abnormal excited behaviour is observed including agitation, nervousness, insomnia.
Inform the doctor or pharmacist of any unwanted and unpleasant effect not indicated previously.
Overdose.
In case of accidental overdosage, gastric lavage may be beneficial and management is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status
Presentation
100ml syrup in amber coloured bottle
Shelf-life
3 years from the date of manufacture.
Storage
Store in a dry place, below 30°C. Protected from light.
Keep out of reach of children.
Distribution category: Prescription Only Medicine (POM).
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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